I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on May 11, 2010

TOWNSEND and TOWNSEND and CREW LLP

By: /Mike L. McGuire/
MIKE L. MCGUIRE

PATENT
Docket No.: 021063-002600US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David K. Swanson

Application No.: 10/727,144

Filed: December 2, 2003

For: CLAMP BASED METHODS AND APPARATUS FOR FORMING LESIONS IN TISSUE AND CONFIRMING WHETHER A THERAPEUTIC LESION HAS BEEN FORMED

Customer No.: 20350

Confirmation No.: 5308

Examiner: Aaron F. Roane

Art Unit: 3769

DECLARATION OF DR. DAVID K. SWANSON UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

I, Dr. David K. Swanson, declare as follows:

1. I have a Masters of Science in Physiology, a Masters of Science in Electrical Engineering, and a Ph.D. in Electrical and Computer Engineering, each from the University of Wisconsin in Madison.

2. I have been employed in the biomedical science field for 35 years and have 30 years of experience in the area of cardiac treatment. I was employed by EP Technologies, Inc. as the Director of Research and Development for Ventricular Tachycardia and Atrial Fibrillation Therapies from 1993 to 2005. I am currently the Chief Technical Officer for Estech, a manufacturer of minimally invasive surgical

devices. My present employer, Estech, is the assignee of U.S. Patent Application No. 10/727,144 ("the present application").

3. I am a named inventor in approximately 200 patent filings relating to electrophysiology and/or electrosurgery. I am also the inventor named in the present application.

4. At the time the subject matter disclosed in the present application was made, I was actively engaged in the practice of researching and designing electrophysiological and electrosurgical methods and devices.

5. At the time the subject matter disclosed in the present application was made, and at all times referenced herein, I was aware of the level of ordinary skill in the art to which the subject matter pertains. I am very familiar with the scientific literature and practices of others in this field. A copy of my CV is attached.

6. I have read the present application and have followed its history.

7. I have reviewed the Office Action dated November 23, 2009 ["Office Action"] and the Advisory Action dated January 14, 2010 ["Advisory Action"]. I have also reviewed US 6,807,968 ["Francischelli"], US 6,277,117 ["Tetzlaff"], US 6,889,694 ["Hooven"], US 6,032,674 ["Eggers"], and US 6,558,408 ["Fogarty"], which the Office Action is relying on to reject presently pending claims of the Application.

8. As I understand, the Office and Advisory Actions allege that it would be obvious to modify Hooven by switching the location of the sensor (168) with the pacing/sensor pair (172/174), and that the modification would provide the same intended functionality.

9. With reference to Fig. 66 of Hooven (partially reproduced below), it is my opinion that the proposed modification would not have been obvious to the artisan at the time I invented the present subject matter, and that the proposed modification would not provide the same functionality intended by Hooven.

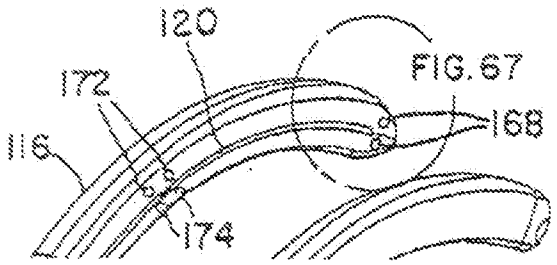

Fig. 66 of Hooven

10. Based on my reading of Hooven, Fig. 66 depicts a curved jaw assembly (116), a fixed electrode (120), a pair of bipolar pacing electrodes (172), and a pair of bipolar EKG electrodes or sensors (174). The distal tip of the fixed jaw (116) includes a pair of laterally-opposed bipolar EKG electrodes or sensors (168) spaced slightly distally from the distal-most end of the electrode (120).

Relocating Hooven's Pacing/Sensing Pair (172/174)

11. As I understand, according to Hooven pacing/sensing continues as electrode (120) delivers ablation energy until such a time sensor (174) no longer detects pacing (172) signal, thus indicating lesion formation. Hence, there is a specific functional reason as to why each of the pacing/sensor pair (172/174) are located on opposing sides of electrode (120). Specifically, the intended functionality of pacing/sensing electrodes (172/172) is dependent upon the lesion being formed in an intervening location between the pacing electrode (172) and the sensing electrode (174).

12. If Hooven's pacing/sensing electrodes (172/174) were moved distal to electrode (120), then electrode (120) would no longer be located between the pair (172/174). As a consequence, the pair (172/174) would not function in the same way

as if they were located on opposing sides of an intervening electrode (120). That is, the pair (172/174) would no longer function in an equivalent manner to determine when the lesion is complete, as described by Hooven. Accordingly, it is my belief that at the time my invention was made, it would not have been obvious to relocate Hooven's pacing/sensing pair (172/174) because this would modify the intended operation stated by Hooven.

Relocating Hooven's Sensors (168)

13. As I understand, Hooven cautions that it is important to monitor the EKG of the distal tip, so that damage to the mitral valve can be avoided. Hooven urges the surgeon to use the distal sensors (168) to monitor the EKG of tissue contacted by the jaw tip, in order to precisely place the jaw tip on the mitral valve annulus, and away from the mitral valve leaflets. Thus, there is a specific functional reason as to why the sensors (168) are located at the distal tip of the jaw member, and the intended usage of Hooven's sensors (168) depends upon those sensors being located at the distal tip of the jaw.

14. If Hooven's sensors (168) were moved away from the tip to a central location, for example to the position of pacing/sensor pair (172/174) on Fig. 66, then sensors (168) would no longer operate as intended, because they would no longer be used to accurately facilitate placement of the jaw tip as described by Hooven.

15. In sum, in order for the device to function according to the stated intentions of Hooven, pacing/sensing electrode pair (172/174) must remain on opposing sides of an intervening electrode (120), and sensors (168) must remain at the distal tip of the jaw. If Hooven were modified by switching the location of the sensor (168) with the pacing/sensor pair (172/174), Hooven would no longer provide the same functionality, and would not be operable as intended.

Benefits of Distally Located Stimulation Element

16. One aspect of my invention involves an apparatus having a coagulation element and a stimulation element, where the distal end of the stimulation element is located distal to a distal end of the coagulation element. Aspects of this feature are shown in the Fig. 24B of the Application (reproduced below).

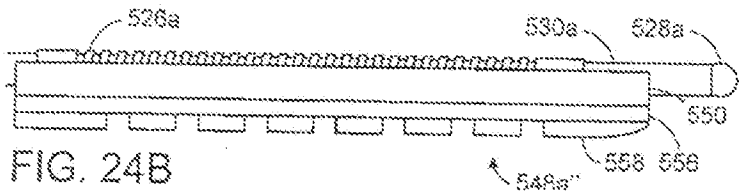

FIG. 24B

17. Specifically, this drawing shows a distal end of stimulation electrode 528a disposed distal to a distal end of coagulation electrode 526a. As explained in the present application at, for example, page 27, lines 31-33, such arrangements allow a physician to test various locations during lesion formation, without moving the probe.

18. During a treatment, tissue directly adjacent to the coagulation electrode becomes heated. However, there is typically a range of temperature (e.g. between about 45° C and about 50° C) where heated tissue does not respond accurately to stimulation, yet has not yet reached the temperature where transmural ablation occurs.

19. Having a stimulation electrode 528a that is disposed distal to the distal end of a coagulation electrode 526a allows for the accurate evaluation of tissue in the vicinity of the treated area, because stimulation electrode 528a can effectively operate even when tissue directly adjacent to coagulation electrode 526a may not respond to stimulation (whether due to high temperature or coagulation). Moreover, such stimulation and evaluation can occur before, during, or after application of the coagulation energy.

20. Hooven's device is limited in this regard, because the pacing electrode (174) is located directly adjacent the ablation electrode (120). As noted above,

because overheated tissue may not respond well to pacing, a pacing electrode that is located directly at the ablation electrode may be ineffective in stimulating the adjacent tissue. Hence, with Hooven's configuration it is not possible to accurately carry out pacing/sensing with pacing/sensor pair (172/174) when tissue directly adjacent the electrode (120) is heated to the point where it no longer responds to pacing, yet is not heated to the point where coagulation has occurred. Such temperatures may occur during or directly following application of ablation energy.

21. Moreover, Hooven's configuration does not provide the capability of administering pacing energy to certain tissue locations during the lesion formation. For example, with Hooven's configuration it is not possible to administer pacing energy to locations that are distal to the distal end of the ablation electrode during a lesion formation.

21. One aspect of my invention is to provide a stimulation electrode that is located away from the coagulation electrode which can effectively stimulate other tissue locations, as those other locations are not directly next to the ablation electrode and are therefore not overheated.

22. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

David K. Swanson — May 10, 2010

Dr. David K. Swanson — Date

David K. Swanson, Ph.D.

1458 Ridgeley Drive
Campbell Ca 95008
dswanson@estech.com

home: (408) 559-3055
work: (925) 543-2116

SUMMARY

Dynamic, highly motivated technical expert with a proven track record of leading project teams from concept phase through full product release. Highly recognized by colleagues and management for innovation in the medical device industry. World class inventor and designer of commercially successful medical devices. Inventor on more than 250 issued US patents.

Excellent communicator with an ability to exchange information with both medical and technical experts. Experienced in providing technical Marketing support for increasing sales of products in newly evolving markets.

TECHNICAL SKILLS

- Technical leadership
- Technical management
- Electro-mechanical design and evaluation of medical products
- Project management
- Patent prosecution and IP strategy

PROFESSIONAL EXPERIENCE

ESTECH San Ramon, CA **2005-present**

Chief Technical Officer
Head of Intellectual Property. Leader of surgical AF medical device development for ESTECH. Serves as primary Business Development contact for ESTECH for both surgeon customers and potential company partners. Defines clinical research strategy and is in charges of all Medical Advisor Agreements.

Boston Scientific Corp San Jose, CA **1992-2005**

Senior R&D Director
Head of Intellectual Property. Leader of all surgical medical device development for the San Jose site. Technical leader of technology evaluation of designs, manufacturing methods or materials that could be useful for the San Jose business (primarily electrophysiology). Primary contact for engineers in other divisions who wanted to leverage technology that San Jose had developed.

- Created highly-effective IP program (most inventions/engineer of all divisions within BSC)
- Led numerous development teams, introducing products that generated more than 50% of the total sales of the EP Division BSC. (Most while I was a manager or director of R&D)
- Provided Marketing support for all products I developed, and most of the EP products that others developed. Provided benchmark testing and white papers to aid in selling our products.
- Inventor on more than 200 issued US patents assigned to BSC.

Cardiac Pacemakers Inc (Guidant) St. Paul, MN **1988-1992**

Group leader, Tachyarrhythmia Research
Development of technologies and algorithms used in AICDs (Implantable Defibrillators)

- Developed arbitrary waveform defibrillator capable of generating up to 50,000 Watts of power for 20 to 50 ms.
- Defined waveform shape that was most effective at defibrillating hearts in Ventricular Fibrillation
- Provided animal data used to design electrogram sensing that was insensitive to the tissue stunning that can occur near to implantable defibrillating leads.
- An inventor on more than 25 issued US patents assigned to Cardiac Pacemakers, Inc.

EDUCATION

PhD Electrical and Computer Engineering, 1976
University of Wisconsin, Madison

M.S. Physiology, 1973
University of Wisconsin, Madison

M. S. Electrical Engineering, 1972
University of Wisconsin, Madison

B.A. Physics, 1970
Northern Illinois University

PROFESSIONAL TRAINING

- Statistical Process Control
- Effective management courses (many)
- Project Management

HONORS

- Distinguished Achievement Award, University of Wisconsin, 2008
- Greatest number of BSC patents (2000, 2001, 2002, 2003, 2004, 2005)
- BSC Science and technology award in 2000
- National honors society, Physics, 1970